



# CENTER FOR FOOD SAFETY

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National Organic Standards Board  
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**Docket No: AMS–NOP–12–0070**

## **Center for Food Safety Comments to the National Organic Standards Board**

The Center for Food Safety (CFS) is a non-profit membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and sustainable agriculture. Our list of True Food Network members has rapidly grown to include over two hundred thousand people across the country that support organic food and farming, grow organic food, and regularly purchase organic products.

Our comments address the following issues: oxytetracycline, polyoxin D zinc salt, excluded methods, sugar beet fiber, other ingredients, confidential business information, and public communications.

### **Crops Subcommittee**

#### **Oxytetracycline**

#### **CFS opposes 2016 oxytetracycline extension**

CFS does not support the Crops Subcommittee recommendation to extend the use of oxytetracycline until 2016. While the Subcommittee’s recommendation includes language early in the document that emphasizes its commitment to phasing-out antibiotic use,<sup>1</sup> the remainder of the text suggests otherwise. The majority position rationalizes the use of antibiotics and minimizes the risks associated with oxytetracycline, presenting an understated and sometimes even misleading picture of the true threats oxytetracycline poses. In addition, the call for “increased support for research”<sup>2</sup> is the same call that the organic community has heard from the NOSB for years, but to no avail. As such, the Subcommittee’s recommendation does not convey to the organic community a strong message or

<sup>1</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline. February 5.

<sup>2</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline. February 5.

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commitment by the NOSB to remove antibiotics from organic production. We urge the NOSB to provide language to accompany its final decision on the petition that clearly states the principle that antibiotics do not belong in organic production systems.

CFS supports the minority position to maintain the existing oxytetracycline expiration date of October 2014 and to reject the petition to extend its use until 2016. As the minority position clearly demonstrates, the use of antibiotics for fire blight control in apple and pear production fails the three applicable NOSB material review criteria mandated by the Organic Foods Production Act (OFPA): (i) environmental and health impacts, (ii) compatibility with organic principles, and (iii) essentiality of the material. This clear and objective assessment of the unacceptability of oxytetracycline in organic provides the necessary and sufficient basis for the eliminating oxytetracycline at the earliest opportunity—the current 2014 expiration date. The NOSB has provided ample warning that oxytetracycline would not be available for organic growers indefinitely, as the original listing in 1995 and all subsequent reviews have clearly indicated. We believe that the intervening 18 years has been enough time for skilled growers to identify the workable cultural practices and substitute materials needed to put the organic apple and pear growing industry on the proper course of organic production.

### **Antibiotic resistance poses human health risks**

The main problem posed by the use of antibiotics in organic apple and pear production is the development and spread of genes for antibiotic resistance. Organic production should not be contributing in any way to the serious threat of losing an important drug to fight human bacterial infections, due to bacterial resistance to the drug. While the majority position heavily focuses its discussion on antibiotic residues that may be left on fruit, an important consumer consideration, we believe that line of argument obfuscates the more critical issue—the mechanisms that create resistance in the orchard environment in the first place.<sup>3</sup> The Subcommittee wrongly minimizes this risk in the face of scientific and medical views to the contrary.<sup>4</sup>

#### *Development of antibiotic resistance*

Antibiotic use inevitably leads to the development of resistance by bacteria, regardless of the intensity or frequency of its use. When bacteria are exposed to antibiotics, susceptible bacteria die and those with resistance survive and increase the incidence of conjugation with other bacteria, effectively enhancing the spread of antibiotic resistance.<sup>5</sup> With respect to the *Erwinia amylovora* bacteria found in organic apple and pear orchards, resistance will eventually emerge to create the conditions that will render antibiotics ineffective for preventing fire blight. Regardless of the decision to extend the expiration date, organic apple and pear growers will lose oxytetracycline as a tool to control fire blight. It is just a matter of time. Surely, this is no surprise to growers who have already confronted resistance to streptomycin, a tool which has lost its effectiveness against fire blight in many regions.

<sup>3</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Majority Position. February 5.

<sup>4</sup> American Academy of Microbiology. 2009. Antibiotic Resistance: An Ecological Perspective on an Old Problem.; Silbergeld, E., J. Graham, and L. Price. 2008. Industrial Food Animal Production, Antimicrobial Resistance, and Human Health. *Annu. Rev. Public Health*, 29: 151-169.

<sup>5</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Minority Position. February 5.

The eventuality of fire blight resistance is not addressed in the majority position, which instead argues against the inevitability of *E. amylovora* developing resistance because “there are no examples of acquisition of tetracycline-resistance genes by *E. amylovora* in orchards.”<sup>6</sup> Yet, the 2011 Technical Review directly states that “there have been reports of oxytetracycline resistant strains of *E. amylovora* in apple orchards, [although] the extent of this resistance is unknown,”<sup>7</sup> and resistant bacteria have been identified in orchards, especially in those with a history of oxytetracycline use.<sup>8</sup> While fire blight itself is already developing resistance, resistant genes do not need to evolve in the fire blight bacterium in order to transfer resistance to other organisms.

#### *Transfer of antibiotic resistance between bacteria*

Horizontal gene transfer (HGT) occurs readily between various species of bacteria and is the main mechanism for spreading antibiotic resistance. The majority position does not adequately present the available science and current thinking with respect to the development of resistance and horizontal gene transfer. The following excerpt from the *Johns Hopkins Magazine* describes the evolving view of microbial genetics and HGT:

“Bacteria have a remarkable capability for sharing genes, through what is known as horizontal gene transfer. The old view of resistance was Darwinian: In the presence of antibiotics, a mutation would be naturally selected if the mutated gene helped a microbe survive application of the drugs. “That underestimates the brilliance of microbes...,” [Dr. Ellen] Silbergeld says. Molecular biologists now understand that within a microbial community, one microbe can acquire genetic material from another microbe, even a microbe of a much different type, then incorporate it in its own genome and thus acquire resistance to an antibiotic it has not yet even encountered. It's as if bacteria are capable of downloading resistance from a gene database.”<sup>9</sup>

In contrast, the majority position argues that there needs to be a direct link between microbial species that are human pathogens and exposure to antibiotics sprayed on apple and pear trees. However, this ignores the ability of reservoirs of resistance to develop, even in benign organisms, which can eventually pass resistance on to human pathogens. This situation can contribute to a crisis in antibiotic resistance if the pathogens do not respond to available antibiotics.<sup>10</sup> Thus, development of resistance within an ecosystem can and does contribute to resistance in human pathogens. HGT between unrelated bacteria can pass resistant genes between orchard species and human pathogens or simply create a reservoir of resistance in the environment that can later be passed to pathogenic species. There are a number of mechanisms that can move microbes out of the orchards and into human communities, including dust on fruit, airborne dust, and dirt on workers’ shoes.<sup>11</sup> These clear linkages

<sup>6</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Majority Position. February 5.

<sup>7</sup> ICF International for NOP. 2011. Technical Review: Tetracycline (Oxytetracycline). April 1, 2011. Lines 577-580.

<sup>8</sup> Schnabel & Jones. 1999. Distribution of tetracycline resistance genes and transposons among phylloplane bacteria in Michigan apple orchards. *Appl. Environ. Microbiol.*, 65: 4898-4907.

<sup>9</sup> Keiger, D. 2009. Pharmacology. *Johns Hopkins Magazine*, available at: <http://www.jhu.edu/jhumag/0609web/farm.html>

<sup>10</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Majority Position. February 5.

<sup>11</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Majority Position. February 5.

between orchard microorganisms and human pathogenic communities exist, even when they are not directly exposed to antibiotics.

### *Soil ecosystem impacts*

Broadcast spraying of oxytetracycline in orchards exposes a wide swath of the orchard to antibiotics, including soil and its microbial population. The impacts of spraying oxytetracycline in orchards contravene OFPA's mandate to 'maintain or improve' the ecosystems where organic farming occurs.<sup>12</sup> Laboratory studies have demonstrated that oxytetracycline application alters soil microbial communities and contributes to oxytetracycline resistance.<sup>13</sup> This alteration in microbial communities is an unacceptable environmental impact in organic systems. When it is applied, oxytetracycline is quickly adsorbed into soil particles and held fairly tightly in the soil structure, but changes in soil conditions (pH, soil organic matter, microbial composition) can eventually result in tetracycline's release into an active form.<sup>14</sup> Thus, the oxytetracycline that accumulates in the soil but remains inactive over a period of time can still have an impact on microbial communities and contribute to further resistance when soil conditions change oxytetracycline into an active form again. Once released into the soil, oxytetracycline can exhibit antimicrobial effects long after it is sprayed. This mechanism for the selection of antibiotic resistance provides a strong argument for phasing out antibiotic use as soon as possible because the effects can persist indefinitely and can be cumulative.

### *Worker exposure to antibiotics and resistance*

Spray applications of antibiotics also provide ample opportunities to expose workers who are mixing and applying the antibiotics. While direct contact with oxytetracycline is not likely to pose an acute hazard, agricultural workers may be more prone to developing and harboring antibiotic-resistant bacteria.<sup>15</sup> This is a direct link between human bacteria and the antibiotics. Even though a direct exposure is not required to build resistance among human pathogens, workers in the orchards can expose human bacteria to antibiotics, contributing to the pool of resistance. If resistant strains do develop, workers can pass these on to their family members and the greater community. While this pathway has not been fully evaluated in the orchard environment, studies from animal agriculture suggest that agricultural workers exposed to antibiotics are at a much higher risk of contracting resistant bacteria.<sup>16</sup>

### **Alternative fire blight controls**

Relying on antibiotics is inconsistent with the spirit of organic production. While there is variation in the severity of fire blight in different years and regions depending upon weather patterns, rain, and humidity, antibiotics are not essential to organic apple and pear production. Oxytetracycline is not strong enough to kill fire blight once infection sets in so it is primarily used prophylactically. The use of other control products when conditions suggest a fire blight infection is imminent can help directly

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<sup>12</sup> 7 CFR 205.200

<sup>13</sup> Popowska, M., A. Miernik, M. Rzczycka, and A. Lopaaciuk. 2010. The impact of environmental contamination with antibiotics on levels of resistance in soil bacteria. *J. Environ. Qual.*, 39: 1679-1687.

<sup>14</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Majority Position. February 5.

<sup>15</sup> ICF International for NOP. 2011. Lines 568-573.

<sup>16</sup> Silbergeld, E., J. Graham, and L. Price. 2008. Industrial Food Animal Production, Antimicrobial Resistance, and Human Health. *Annu. Rev. Public Health*, 29: 151-169.

replace the use of oxytetracycline as a preventative measure. There are a variety of other ways that fruit growers can protect their orchards from fire blight and reduce its spread, including planting resistant cultivars and rootstocks, adequate tree spacing, and the use of alternative control products.<sup>17</sup> As part of a holistic approach to disease control in orchards, there are also a number of existing and emerging alternative products available. Some of the alternatives that can be used include foliar nutrient sprays, copper materials while trees are dormant, lime sulfur, and Serenade MAX.<sup>18</sup> The recent registration of Blossom Protect, a natural yeast product with promising results, adds to the alternatives available to growers. The most effective alternative controls require an integrated approach including cultural practices, attention to fire blight prediction models, and alternative biological control products.

Growers who sell to the European Union and Canada also do not use antibiotics because it is prohibited in tree fruit production there. This includes almost one third of Washington State's organic apple producers in 2011.<sup>19</sup> The success of these growers shows that antibiotics are not an essential input in organic systems, but the challenge for those who still use oxytetracycline is to learn how to adapt such tried and true practices to fit their own growing conditions. The inconsistency is also an issue for equivalency agreements with other countries' organic programs. Once organic growers cease using antibiotics, these markets will be open to all American growers. The NOSB should allow the use of antibiotics to expire in order to bring U.S. regulations in line with the international community's regulations on antibiotics.

### **Consumers demand organics without antibiotics**

Consumers choose to buy certified organic food because they want to support systems of production that protect and enhance human health and the environment. They also expect their organic food to be grown without the use of antibiotics, growth hormones, genetically engineered organisms, and synthetic herbicides and pesticides.<sup>20</sup> Spraying organic apple and pear orchards with oxytetracycline, a drug that the World Health Organization (WHO) has labeled a "critically important"<sup>21</sup> antibiotic for human health, undermines the spirit and intent of organic consumer expectations. Despite the fact that oxytetracycline has been on the National List (NL) for several decades, few people other than NOSB insiders know that antibiotics are used in organic apple and pear production. But, this latest petition for extension, coupled with the Subcommittee's faulty scientific assessment that minimized the threat of antibiotic resistance, has sparked a public discussion about why antibiotics are being used in organic at all. This little-known fact about organic that now has been made public has the potential to not only tarnish the organic apple and pear industry, but also to tarnish the organic label and reputation of the wider organic sector.

And, in case there is any doubt that widespread consumer market rejection could happen, it would behoove those pushing for another extension to recall the so-called "Alar apple scare" that swept the

<sup>17</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Minority Position. February 5.

<sup>18</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Minority Position. February 5.

<sup>19</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline, Minority Position. February 5.; ICF International for NOP. 2011. Lines 222-230.

<sup>20</sup> Organic Trade Association. 2011. U.S. Families' Organic Attitudes & Beliefs, 2011 Tracking Study. Page 13.

<sup>21</sup> World Health Organization. 2009.

country in 1989. A *60 Minutes* program exposed the dangers of spraying the toxic chemical, Alar, on apples to make them ripen longer on the tree before falling to the ground. That exposé ushered in one of the country's most widespread and costly food scares, which resulted in the collapse of the apple market, virtually overnight. Researchers found residues of the probable human carcinogen in several brands of baby food, which marked the last straw for consumers. They stopped buying apples, apple juice, and products containing apple ingredients. Prices plummeted, and the nation's largest apple growing region, Washington State, claimed losses of \$100M and a slew of small grower bankruptcies. EPA finally banned Alar shortly thereafter, citing the "unacceptable public health risk" as the justification for its decision.<sup>22</sup> Although the apple industry eventually bounced back, it was at a huge cost to growers. There are no guarantees that this would be the case with respect to antibiotics in organic apples and pears.

While admittedly the controversy surrounding oxytetracycline use is different because the public health concern is the development of antibiotic resistance, not toxic pesticide residues in fruit, the outcome of consumer rejection could be the same if action is not taken. Organic production systems depend upon the existence of organic markets for their economic survival, and given the fact that 24,545 people have signed CFS's petition to oppose the extension thus far, the organic apple and pear market could be at risk if growers again strongly protest the 2014 phase-out date.

The non-therapeutic use of antibiotics in organic production systems also presents an unacceptable public health risk. It contravenes the NOSB's stated Principles of Organic, which emphasize promoting and enhancing "biological cycles" and "the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials."<sup>23</sup> As the problems associated with antibiotic resistance and the potential for reduced effectiveness of this important drug for curing human infections, the obvious question that must be asked is why antibiotics are being used by organic growers in the first place. Isn't it antithetical to the principles of organic? A strong commitment from the NOSB to uphold the 2014 expiration date would send a meaningful signal to organic consumers that the NOSB is committed to continual improvement, as per the regulatory charge of the National Organic Program.<sup>24</sup>

### **No need to wait for EPA review**

Most materials that are approved by EPA as pesticides are not permitted in organic production because they fail to meet the strict review criteria under OFPA. Oxytetracycline pesticides are currently under registration review with the EPA, which requires new data gathering and analysis and is scheduled for completion in 2014.<sup>25</sup> The majority position suggests that an extension until 2016 will allow NOSB to evaluate new EPA data, but this is unnecessary to fulfill OFPA's stricter review criteria. While some of the findings from the registration review may help expand the understanding of tetracycline's impacts, the EPA review process is not reason enough to delay action at the NOSB. The information that is already available on tetracycline use and persistence in orchards provides a

<sup>22</sup> Gordon, W. 2011. The True Alar Story: Part I. Available at: <http://www.onearth.org/blog/the-true-alar-story>; Environmental Working Group. 1999. Ten Years Later, Myth of 'Alar Scare' Persists. Available at: <http://www.ewg.org/node/8005>

<sup>23</sup> NOSB. October 17, 2011. "NOSB Principles of Organic Production and Handling.

<sup>24</sup> 7 CFR 205.200.

<sup>25</sup> NOSB Crops Subcommittee. 2013. Petitioned Material Proposal: Oxytetracycline. February 5.

sufficient scientific rationale for the NOSB to take precautionary action and support the expiration of oxytetracycline for use in organic apple and pear production.

### **Conclusion**

CFS urges the NOSB to vote against extending the use of oxytetracycline to 2016. Increasing, documented incidence of antibiotic resistance and the threat of losing oxytetracycline as a tool for combating infections in humans, alone, is reason enough to prohibit its use in organic at the earliest opportunity.

### **Polyoxin D Zinc Salt**

CFS supports the Crops Subcommittee recommendation to deny the petition for listing polyoxin D zinc salt to be used as a fungicide. We agree with the Crops Subcommittee that the zinc salt added to the compound should be considered synthetic because its origin is not specified as mined or recycled. Polyoxin D zinc salt (PDZ) fails to meet the criteria for listing on the National List because it has negative environmental impacts, it is incompatible with organic systems, and it is not essential. CFS believes that the compound is inconsistent with organic production.

PDZ inhibits the chitin synthetase in fungus and can have detrimental impacts on other beneficial insects.<sup>26</sup> As it is a broad spectrum fungicide, CFS has real concerns about its residual negative effects in soil and its adverse impacts on beneficial soil organisms. Fungi serve important functions within soil ecosystems, particularly as decomposers that help to maintain soil structure and break down organic matter and in making nutrients available to crops. These crucial soil organisms would also be affected by the use of products that inhibit chitin formation, even if they are targeting plant pathogenic fungi. PDZ has been shown to affect chitin synthetase in studies on cockroaches as well, suggesting a potentially negative impact on beneficial insects that have a chitin exoskeleton.<sup>27</sup> Without the full ability to synthesize chitin, insects that rely on chitin as a major exoskeleton component will be adversely affected because their structure will not develop properly.

Organic pest management systems rely on interactions of beneficial organisms to provide controls for plant pathogens in a system that “promotes and enhances biological diversity, biological cycles, and soil biological activity.”<sup>28</sup> Introducing the synthetic PDZ input would unnecessarily and adversely affect these natural cycles. Polyoxin D zinc salt is also not essential for organic production in that there are several readily available alternative products and practices identified in the technical review. These include crop rotation, nutrient management, sanitation, and selection of resistant species and varieties.<sup>29</sup>

We urge the NOSB to reject the petition for listing polyoxin D zinc salt.

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<sup>26</sup> NOSB. 2013. Crops Subcommittee Petitioned Material Proposal: Polyoxin D Zinc Salt. Jan. 29. 2013.

<sup>27</sup> The Organic Center for NOP. 2012. Technical Evaluation Report: Polyoxin D Zinc Salt. Lines 257-262.

<sup>28</sup> NOSB. 2001. Principles of Organic Production and Handling: Section 1.1. October 17.

<sup>29</sup> The Organic Center for NOP. 2012. Technical Evaluation Report: Polyoxin D Zinc Salt. Lines 367-382.